

ATTACHMENT 15

**HANDOUT FOR PRESENTATION
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THE BURDEN OF EXPOSURE OF CANADIAN BLOOD DONORS TO BEEF PRODUCTS ORIGINATING FROM THE UNITED KINGDOM. Marc Germain, MD, PhD, Héma-Québec. JoAnne Chiavetta, PhD, Canadian Blood Services. (May 18, 2000)

The following document summarises the approach taken by the Canadian Blood Services (CBS) and Héma-Québec (H-Q) to assess the exposure of Canadian blood donors to beef products originating from the United Kingdom but consumed outside that country. The results of this analysis will be used to re-examine the current deferral policy for donors who may have been exposed to BSE contaminated food products.

Background

Approximately 1 million blood units are collected in Canada annually, with one quarter collected by H-Q in the Province of Quebec. CBS and H-Q collect, test and distribute all blood used in Canada, serving a population of over 31 million Canadians.

On September 30th, 1999, CBS and H-Q introduced a new deferral criterion for donors who travelled to the UK. For the CBS, donors who spent a cumulative duration of 6 months or more since 1980 are now permanently deferred, while for H-Q the cumulative duration threshold is one month. Based on a donor survey conducted in 1999, it was estimated that such criteria would result, for each organisation, in the loss of approximately three percent of blood donors.

The decision to target the UK exclusively was then based on the observation that the vast majority of BSE cases occurred in that country. Although it was recognised that significant quantities of these products may have been exported, there were no good data to quantify the level of exposure to UK beef outside the UK.

In France, a risk assessment was recently conducted by the "Agence française de sécurité sanitaire des produits de santé" to evaluate the possible exposure of blood donors to the BSE agent. The analysis considered the exposure resulting from UK travels, but also the exposure to bovine products imported from the UK. Based on data obtained through the French ministries of Agriculture and Finance, the authors estimated that 5-10% of all beef products consumed in France between 1980 and 1996 originated from the UK. Because of the magnitude of this exposure and the small number of BSE cases in France, the contribution of indigenous BSE was considered to be negligible.

Finally, since the beginning of the epidemic, three vCJD cases have been reported in France (two of which are officially confirmed), in people who have never travelled to the UK. According to most experts, the likely source of exposure to the vCJD agent was the consumption of BSE contaminated food, the exact source of which (indigenous or imported) cannot be determined.

Estimations and assumptions in the CBS/H-Q analysis

Based on the French risk assessment and UK data on live bovine exports (HM Customs and Excise), we estimated the proportion of the total beef product consumption that may have been attributable to UK imports, in countries other than France. In the analysis, we only included countries for which this proportion was judged to be significant, i.e. France (5-10%) and the Netherlands (9-17%). Taken together, these countries represent more than 80% of all UK live bovine exports during the period 1980-90.

In addition to the usual assumptions regarding vCJD, we postulated that:

- 1- For the same level of exposure, the risk of acquiring vCJD is similar whether the UK BSE contaminated products are consumed within the UK or outside the UK, i.e. we did not consider possible differences in the types of bovine products, in their mode of transformation or preparation, or in the age distribution of the animals from which the products were derived.
- 2- In countries other than the UK, consumption of beef products contaminated with indigenous BSE was considered to be negligible in comparison with beef products of UK origin.
- 3- In the absence of any good data, the re-exportation of UK beef products from non-UK countries was also considered to be negligible.

- 4- For a donor having travelled to a country where UK beef products could be consumed, the risk of vCJD infection is directly proportional to the amount of time spent in that country, with a correction factor equivalent to the proportion of the total beef product consumption that was of UK origin (the maximum intensity of exposure being in the UK).

The travel habits of blood donors to countries affected by BSE were obtained from the surveys conducted by CBS and H-Q in 1999, and the calculations apply to the situation that existed prior to the implementation of the current deferral criteria for UK travel.

Impact of various deferral criteria on the number of donors and the reduction of the total burden of exposure to UK beef products (Canadian Blood Services and Héma-Québec)

DEFERRAL CRITERION (Country / duration of stay)			Proportion of all donors (%)		Reduction of overall person-time exposure (%)	
UNITED KINGDOM	FRANCE	NETHERLANDS	CBS	H-Q	CBS	H-Q
≥ 1 day	-	-	21.8	12.4	94.3	74.7
≥ 1 day	≥ 6 month	≥ 6 month	21.6	13.5	98.0	94.3
≥ 1 day	≥ 1 year	≥ 1 year	21.5	13.1	97.7	92.8
≥ 1 month ¹	-	-	11.4	3.0	89.2	65.3
≥ 1 month	≥ 1 month	-	12.1	9.2	91.2	85.7
≥ 1 month	≥ 6 month	-	11.5	5.0	90.9	83.1
≥ 1 month	≥ 1 year	-	11.5	4.5	90.7	81.8
≥ 1 month	≥ 1 month	≥ 1 month	12.8	9.4	93.6	87.7
≥ 1 month	≥ 6 month	≥ 6 month	11.7	5.1	93.0	85.0
≥ 1 month	≥ 1 year	≥ 1 year	11.5	4.6	92.6	83.4
≥ 6 months ²	-	-	2.5	1.1	67.2	55.1
≥ 6 months	≥ 6 months	-	3.0	3.1	68.9	72.9
≥ 6 months	≥ 1 year	-	2.8	2.5	68.7	71.6
≥ 6 months	≥ 6 months	≥ 6 months	3.2	3.3	70.9	74.7
≥ 6 months	≥ 1 year	≥ 1 year	2.9	2.7	70.6	73.2

¹Current criterion for H-Q. ²Current criterion for CBS.

Discussion

These estimates are based on numerous assumptions and should only be viewed as approximate at best. However, they provide a rational basis for evaluating whether Canadian blood donors may have been significantly exposed to UK beef products in countries other than the UK, and the extent to which their deferral from donation may impact on the overall exposure to these food products. As with the UK deferral criterion, this impact is very much dependant on the travel habits of a particular donor population. The decision whether to modify the current criterion will depend on several factors, including the potential impact on exposure reduction and the capacity of each blood agency to compensate for yet another loss of donors.

THE RESULTS OF DEFERRAL OF CANADIAN BLOOD DONORS DUE TO TRAVEL TO COUNTRIES ENDEMIC FOR BOVINE SPONGIFORM ENCEPHALOPATHY (BSE). JoAnne Chiavetta, PhD, Canadian Blood Services, Marc Germain, MD, PhD (May 19th, 2000).

This document is a summary of the first seven months of a vCJD permanent deferral for donors for CBS and H-Q.

Canadian Blood Services (CBS)

At CBS donors who have spent a cumulative time of more than six months of any country in the United Kingdom (UK) since 1980 were permanently deferred as of September 30th, 1999. Prior to this implementation, surveys were carried out in order to estimate the proportion of donors who might have been lost if such a deferral was put in place. A CBS survey of 8,026 donors was conducted in February of 1999. It showed that 21.8% reported ever having been in the UK since 1980, with 2.5% indicating they had spent a cumulative time of more than six months there. It was estimated that deferral of these donors would result in a loss of approximately 17,500 units from the approximately 700,000 units collected annually. Prior to the implementation of the deferral, letters were sent to all donors indicating this new deferral criterion. Of 942 who then telephoned the CBS regarding the vCJD deferral 747(79% of those who telephoned) were then deferred based on their travel history.

During the 1st month after deferral was implemented 1.3% of our donors were deferred in our clinics because of UK travel history. This was approximately half of that estimated by the survey. The rate of deferral dropped steadily to 0.2% of donors attending clinics in April 2000, less than one twelfth of what was originally estimated. What remains unknown is the proportion of donors who were silently lost because of their awareness of the UK travel deferral and subsequently elected not to donate. Most important is the possibility that the specific criterion of this deferral (1980 forward; more than six months) was not understood by many donors electing not to donate. For example, it is not known whether donors who were born in the UK but did not live there since 1980 might incorrectly consider themselves ineligible. As part of a surveillance project, donors who have not returned since the implementation of the UK deferral are being contacted in order to determine their reasons for not returning to donate, in particular whether this lapse could be due to a misunderstanding of the UK travel deferral criteria.

Hema-Quebec (H-Q)

Since September 30th, 1999 H-Q donors who spent a cumulative duration of 30 days or more in the UK (since 1980) are permanently deferred. A survey conducted in early 1999 indicated that 3.0% of donors would be affected by this criterion. During the first month following the implementation of this new policy, 1.0% of donors presenting for donation were deferred because of a history of travel to the UK. After three months, this proportion had fallen to 0.6%, suggesting that a fair proportion of donors self-deferred. However, only 4-5% of current donors report having travelled to the UK for less than 30 days, which is approximately half the proportion observed in the survey.

Summary

Overall, it is likely that the actual number of donors lost due to the vCJD deferral policies at each blood service is underestimated. This may be due to self-deferral of potential donors who perceive themselves as ineligible to donate due to travel to/residence in BSE affected countries.